



THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Patent application of
Man C. Niu

Serial No.: 09/740,582

Group Art Unit 1638

Filed: December 19, 2000

Examiner: Stewart F. Baum

For: METHODS FOR EFFECTUATING
mRNA TRANSFER OF GENETIC
INFORMATION BETWEEN SPECIES
AND PRODUCT OF THE SAME

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Commissioner for Patents
Washington, D.C. 20231

DECLARATION OF MAN C. NIU PURSUANT TO 37 C.F.R. 1.132

Sir:

I, Man C. Niu, being duly sworn according to law, hereby depose and say
as follows:

I am a citizen of the United States of America, residing at 7950
Montgomery Avenue, Elkins Park, PA 19027 and am the sole inventor of the
methods disclosed and claimed in the patent application referenced above.

I hold the following degrees: Bachelor of Science in Biology from Peking
University in Peking, China and a Ph.D. in Biology from Stanford University in
Palo Alto, California.

My relevant professional experience includes being employed as a Biologist at Stanford University, being on the staff as an Assistant Professor of General Physiology at Rockefeller University in New York, New York, being a Professor of Biology at Temple University in Philadelphia, Pennsylvania and the Director of the Niu Laboratory, Peking, China. The Niu Laboratory in Peking, China is engaged in research and development respecting various aspects of botany and biology with the emphasis being in beneficial genetic alteration of plants for animal and human consumption.

I have authored or co-authored nearly one hundred (100) scientific papers which have appeared in leading journals, worldwide, over the past 20 years.

I believe a person of ordinary skill in the art, upon reading the patent application referenced above would immediately appreciate the usefulness of the invention disclosed and claimed in the patent application based on the elimination of experimental protocols for introducing foreign, i.e. non-indigenous, DNA to obtain transgenic plants, which protocols are known to persons of ordinary skill in the art to be laborious, time-consuming and produce variable, inconsistent results. In contrast, the invention disclosed and claimed in my above-referenced patent application provides a simple, easily performed method for producing transgenic plants by introducing foreign mRNA thereinto. The resulting transgenic plants are capable of synthesizing a protein in subsequent generations based on the transfer of genetic information via mRNA molecules.

I believe genetically transformed plants producing highly desirable proteins are economically important and commercially desirable. One of skill in

the art would appreciate the large amount of work that is eliminated in using the methods of the invention as disclosed and claimed in the above-referenced application to obtain protein, i.e. soy globulin protein, and the commercial viability of the resultant protein.

I performed the immunoassays illustrated in Figures 1 through 6 of the application referenced above. The immunoassays accurately illustrate the pharmacological activity of the soy globulin protein produced by transgenic plant obtained by the method of the invention.

I have reviewed the Hansen reference and believe it is an accurate general survey of transformation methods which were known at the time the article was written. The article does not mention use of transformation based on mRNA in transgenic plants and therefore, does not anticipate, foreshadow or render obvious the methods of the invention disclosed and claimed in the above-referenced application.

I have reviewed the Songstad article concerning using full cDNA in microinjection. However, the techniques in the Sognstad article do not involve mRNA, but rather involve the full complement of DNA. I believe that the problems noted by the article are overcome by the use of mRNA rather than the full complement of DNA.

I have used the microinjection techniques described in my application and have been successful in producing transgenic plants that produce soy globulin protein.

I direct the examiner's attention to the articles listed on pages 1 and 2 of the specification, which clearly illustrate the success of microinjection procedures using mRNA.

I did not encounter any problems concerning degradation of mRNA by ubiquitous enzymes using the methods disclosed and claimed in my application referenced above.

I, the undersigned, Man C. Niu, hereby declare that all statements of fact made herein are true and that all statements herein made on information and are believed to be true and further that I know that willful false statements and the like so made herein are punishable by fine or imprisonment or both under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of United States patent application 09/740,582, and/or the validity and enforceability of any patent issuing from such application.

Date: *July 18, 2003*

Respectfully submitted,

Man Chiang Niu
Man C. Niu